REMARKS

This is responsive to an Office Action mailed on December 13, 2010 which finally rejected claims 1, 13-16, 23-27, 29, 31 and 32. Applicant has amended claims 1, 13-15, 27 and 29. Claims 17-22, 28 and 30 were withdrawn from consideration. The application currently includes claims 1 and 13-32.

Applicant's attorney, Peter J. Ims, would like to thank Examiner Klinkel for taking the time to discuss the claim rejections in this matter on January 28, 2011. Examiner Klinkel and Mr. Ims discussed amendments to the claim language which would possibly overcome the 35 U.S.C. §112, second paragraph rejection. It was also discussed to amend the claims to the claims to positively recite the claim elements of the claimed method beyond the recitation of the preamble of claim 1. Further discussions were had to separate or to distinguish a population of patients being treated with the method defined in claim 1 relative to the disclosure of Moulinoux et al. (CA 21645481).

Claims 13-15, 27 and 29 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards is the invention. With respect to claims 13-15, it was asserted that "less than" requires an amount to be less than x but the word "about" includes values larger than x and that the two phrases contradict each other. Applicant has removed the word "about" from the claim language to overcome this rejection.

With respect to claims 27 and 29, it was asserted that the claim element for a sufficient quantities of vitamins, minerals and electrolytes should likely satisfy the daily nutritional needs of the human being is unclear what quantities of vitamins, minerals and electrolytes are required to these claims. Applicant has amended claims 27 and 29 to claim that the quantities of vitamins, minerals and electrolytes satisfy the nutritional needs of a human being to be sustained for a day. Applicant respectfully submits that claims 27 and 29 comply with 35 U.S.C. §112, second paragraph. Withdrawal of the rejections of claims 13-15, 27 and 29 under 35 U.S.C. §112, second paragraph are respectfully requested.

The Office Action rejected claims 1, 13-16, 23-27 29 and 31-32 under 35 U.S.C. §102(b) as being anticipated by Moulinoux et al. Specifically with respect to claim 1, the Office Action asserted that Moulinoux et al. teaches a composition that can be ingested by man which contains less than about 1600 picomoles/g of polyamine and the specific components of the composition are disclosed in Moulinoux et al. With respect to claims 31-32, the Office Action alleged that the composition in Moulinoux et al. may be administered in a dry form to be dissolved extemporaneously in a neutral vehicle suitable for oral or internal administration. With respect to claims 27 and 29, the Office Action alleged that Moulinoux et al. teach administering compositions with the claimed amounts of glucides, lipids, etc. The Office Action also indicated that the polyamine deficient compositions administered are known to induce a powerful antalgic effect in Moulinoux et al. and that the compositions and experiments showing the antalgic effect of these compositions are identical to those of the instant specification. The Office Action stated that the preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. The Office Action concluded that because Moulinoux et al. teaches administering compositions identical to those instantly claimed to humans for the same purpose, the claims are anticipated.

Applicants assert that the instantly claimed invention is a new use of a polyamine deficient daily food ration composition. The claimed invention relates to the prevention of chronic pain while Moulinoux et al. relates to the alleviation of pain that is already being experienced. The prevention of chronic pain has also been recited in the body of the claim as well as in the preamble.

The disclosure of Moulinoux et al. does not disclose the use of the polyamine deficient food ration which results in the prevention of chronic pain as claimed. Rather the composition in Moulinoux et al. is used as an analgesic (or antalgic) as stated by the Examiner and is related to the reduction of already experienced pain through the activity of nociceptive pathways.

The present invention claims the use of the polyamine deficient diet composition as an anti-hyperalgesic and is related to the inhibition of the overactivation of specific "facilitatory systems" which prevents the onslaught of chronic pain. Applicants have previously attached a Declaration under 37 C.F.R. 1.132 in which the differences between analgesic effect (nociceptive) and anti-hyperalgesic effect (facilitatory systems) are discussed. The Declaration also includes additional experimental data that distinguishes between these two effects. The Declaration includes a detailed discussion of the two pathways but the main concepts are discussed herein in the context of the §102(b) rejection.

Applicants assert that the claim for an effect on the NR2-B subunit of the NMDA receptor, i.e. the "anti-hyperalgesic effect" for polyamine deficient compositions is different from the previous claim "analgesic effect" as indicated in Moulinoux et al. as the claimed invention prevents chronic pain while Moulinoux et al. discloses the treatment of pain that is being experienced. According to current understanding of pain relief, it is necessary to distinguish between analgesic effect which is defined by an acute decrease of pain sensation related to a tissue injury (see Fig.1, effect 1 in previously submitted Declaration) and anti-hyperalgesic effect which is the specific reduction of pain sensitization process (pain facilitatory systems) which induce exaggerated pain sensation (hyperalgesia) in response to a given nociceptive stimulus (see Fig.1, effect 2 of the previously submitted Declaration) or abnormal pain sensation in response to a non-nociceptive stimulus (allodynia).

In fact, these two therapeutic effects are related to two different neurophysiologic processes: the first one (analgesia) is related to the reduction of the activity of nociceptive pathways, and the second one (anti-hyperalgesia) is related to the inhibition of the overactivation of specific "facilitatory systems", which are <u>different from nociceptive pathways</u>**,** and lead to pain hypersensitivity (exaggerated pain sensation). It is noteworthy that it is now well admitted that these last systems, *i.e.*, pain facilitatory systems, play a critical role in the development of chronic pain.

Applicants assert that these differences between analgesia and anti-hyperalgesia were not known in the 90's when Moulinoux et al. was filed and would not be utilized by the same

populations. Therefore, specific experimental models (as clinical approaches) to differentiate hyperalgesia from analgesia were not developed in 1993, leading to the impossibility to distinguish and to claim anti-hyperalgesia from analgesia and therefore to claim for an anti-hyperalgesic effect of PDD (Polyamine Deficient Diet, according to the Moulinoux et al. invention) in 90's.

Furthermore, Moulinoux et al. could not suggest the anti-hyperalgesic effect of the treatment because the test did not study the evolution of pain on the time span but just the instantaneous response to a stimulus. In fact, in Moulinoux et al., the conditions of the experiment could not enable the existence of the anti-hyperalgesic effect and therefore the anti-hyperalgesic effect could not be determined.

Applicants assert that in Moulinoux et al. the food compositions described were used to demonstrate analgesic effects. Anti-hyperalgesic mechanisms were not even understood to be separate from analgesic effects. Furthermore, the anti-hyperalgesic effects were neither contemplated nor tested in Moulinoux et al. Applicants were the first to discover the use of the polyamine deficient food rations as a method for affecting the NR2-B subunit of the NMDA receptor. The instant Specification is the first to disclose a method for treating a variety of syndromes or pathologies involving the NR2-B subunit of the NMDA receptor.

Applicants arguments are supported by the Declaration of Guy Simonnet that was filed on June 7, 2010 which clearly illustrates that an anti-hyperalgesic effect of the claimed invention is the result of a different mechanism than that of an analgesic effect. As such, a different group of people would be treated with the method of the present invention. Applicant further incorporates the Remarks that were filed on June 7, 2010 as also further clearly distinguishing the claimed invention over what was disclosed in Moulinoux et al.

The disclosure of Moulinoux et al does not disclose the use of the polyamine deficient food composition as claimed in the present invention principally due to the fact that the present invention relates to the prevention of chronic pain while Moulinoux et al. relates to the treatment of pain that is being experienced. In light of the above discussion and claim amendments, Applicants respectfully request the removal of the rejections based on 35 U.S.C. 102(b).

It is believed that the claims, as amended, are patentable over the prior art, and a Notice of Allowance is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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